

Integra Spine

Vu c-POD™ IBF Device

6/7/2011

AUG - 2 2011

**510(k) Summary**

**Manufacturer:** Integra Spine  
1153 Medina Road  
Medina, OH 44256

**Device Trade Name:** Vu c-POD Intervertebral Body Fusion Device

**Contact:** Dale Davison  
Vice President, Engineering  
Integra Spine  
1153 Medina Road  
Medina, OH 44256  
Office: 330.239.7700  
Fax: 330.773.7697

**Classification:** §888.3080

**Class:** II

**Product Code:** ODP

**Indications For Use:**

The Vu c-POD Intervertebral Body Fusion Device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease (DDD) at one level from C2-C3 to C7-T1. Cervical degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history of radiographic studies. The Vu c-POD implants are to be used with autogenous bone graft and implanted via an open, anterior approach. The cervical device is to be used in patients who have had six weeks of non-operative treatment. The Vu c-POD Intervertebral Body Fusion Device is intended for use with supplemental internal fixation systems, such as the Theken Spine Manta Ray or the Theken Spine Tether systems.

**Device Description:**

The Vu c-POD Intervertebral Body Fusion Device consists of cervical spinal interbody fusion devices as well as instrumentation designed specifically for the implantation of these devices. The Vu c-POD Intervertebral Body Fusion Device is manufactured from PEEK OPTIMA LT1 polymer. The Vu c-POD Intervertebral Body Fusion Device is for single level anterior spinal use from the C2-C3 to C7-T1 disc levels.

**Predicate Device(s):**

The Vu c-POD Intervertebral Body Fusion Device was shown to be substantially equivalent to the previously cleared Vu c-POD Intervertebral Body Fusion Device, K101363, SE 12/16/2010 and has the same indications for use, design, and function.

**Performance Standards:**

Preclinical testing has been performed per ASTM F2077 and ASTM F2267 indicating that the Vu c-POD Intervertebral Body Fusion Device is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Integra Spine  
% Mr. Dale Davison  
Vice President, Engineering  
1153 Medina Road  
Medina, Ohio 44256

AUG - 2 2011

Re: K111675

Trade/Device Name: Theken Spine Vu c-POD Intervertebral Body Fusion Device  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: ODP  
Dated: July 18, 2011  
Received: July 19, 2011

Dear Mr. Davison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
And Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K111675Device Name: **Theken Spine Vu c-POD Intervertebral Body Fusion Device**

The Vu c-POD Intervertebral Body Fusion Device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease (DDD) at one level from C2-C3 to C7-T1. Cervical degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history of radiographic studies. The Vu c-POD implants are to be used with autogenous bone graft and implanted via an open, anterior approach. The cervical device is to be used in patients who have had six weeks of non-operative treatment. The Vu c-POD Intervertebral Body Fusion Device is intended for use with supplemental internal fixation systems, such as the Theken Spine Manta Ray or the Theken Spine Tether systems.

Prescription Use ✓  
(Part 29 CFR 801 Subpart D)

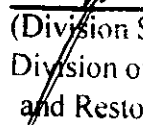
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(29 CFR 801 Subpart C)

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OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K111675